



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20531
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/852,093	05/10/2001	David F. Nellis	0942.5110000	4759

26111

7590

08/01/2002

STERNE, KESSLER, GOLDSTEIN & FOX PLLC
1100 NEW YORK AVENUE, N.W., SUITE 600
WASHINGTON, DC 20005-3934

EXAMINER

LU, FRANK WEI MIN

ART UNIT

PAPER NUMBER

1634

DATE MAILED: 08/01/2002

G

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/852,093

Applicant(s)

NELLIS ET AL.

Examiner

Frank Lu

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 May 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of.
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Art Unit: 1634

DETAILED ACTION

Election/Restriction

1. Applicant's election without traverse of Group I, claims 1-12 in Paper No. 5 is acknowledged.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Note that claim 2-12 are dependent on claim 1.

Claim 1 is rejected as vague and indefinite because it is unclear how intensity value of each fragment corresponds to catalytic activity of a test aliquot since the method of claim 1 does not include an enzyme or does not have a enzymatic digestion step to generate one or more fragments. Please clarify.

Claim Rejections - 35 USC § 102/103

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

Art Unit: 1634

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 1 and 10 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Aultman *et al.*, (Eur. J. Biochem., 124, 471-476, 1982).

Note that this rejection was made in view of the ambiguity of claim 1.

Aultman *et al.*, teach partial P_i nuclease digestion as a probe of tRNA structure. A mixture of 5'-³²P-labeled tRNA and an amount of unlabeled tRNA was digested with P_i nuclease. At different time points, an aliquot sample was taken from the mixture to stop the digestion reaction. The samples from different time points were lyophilized and electrophoresed in a

Art Unit: 1634

polyacrylamide gel. The tRNA digested fragments labeled with ^{32}P as recited in claim 10 were visualized by autoradiography and the fragments in autoradiography films were scanned with a Helena Quick Scan densitometer. For example, in Figure 4, the average percentage of the total readable band intensity for groups of fragments with different 3' termini corresponded to cleavage activities of P_1 nuclease (see pages 471-475 and Figures 2-4). Note that: (1) the samples from different time points were considered as test aliquots as recited in claim 1; (2) the polyacrylamide gel was considered as a separation medium as recited in claim 1; (3) the process that scanned the fragments in Figure 3B was considered as capturing an image of the fragments as recited in claim 1; and (4) although Aultman *et al.*, did not teach directly to measure intensity values from each fragment as recited in claim 1, in the absence of convincing evidence to the contrary, this limitation was considered to be inherent to the reference taught by Aultman *et al.*, since they scanned whole autoradiogram film (see page 472, right column).

7. Claims 1 and 8 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Kandzia *et al.*, (Planta, 204, 383-389, 1998).

Note that this rejection was made in view of the ambiguity of claim 1.

Regarding claim 1, Kandzia *et al.*, teach purification and characterization of lanatoside 15'-O-acetylsterase (LAE) from *Digitalis lanata* Ehrh. Figures 3 A and 3B showed the correlation between different fractions of LAE and their LAE activities. Note that: (1) the samples from fraction 3-8 in Figure 3B were considered as test aliquots and the polyacrylamide gel run under nondenaturing conditions was considered as a separation medium as recited in

Art Unit: 1634

claim 1 since the samples from fraction 3-8 (containing LAE) were loaded into the polyacrylamide gel; and (2) although Kandzia *et al.*, did not teach directly to capture an image of the fragments to measure intensity values from each fragment as recited in claim 1, in the absence of convincing evidence to the contrary, this limitation was considered to be inherent to the reference taught by Aultman *et al.*, since the process that scanned qualitatively LCE (the fragments) in polyacrylamide gel by human eyes could be considered as qualitatively capturing the image of the fragment (see page 384, 386, and 387 and Figure 3).

Regarding claim 8, the polyacrylamide gel run under nondenaturing conditions was stained with Fast Blue B until intense violet bands occurred (see page 384, right column).

Conclusion

8. Claims 2-7, 9, 11, and 12 appear to be allowable if applicant could overcome the rejection under 35 U.S.C. 112 and rewrite them in independent form including all of the limitations of the base claim and any intervening claims.

9. No claim is allowed.

10. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is either (703) 308-4242 or (703)305-3014.

Art Unit: 1634

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (703) 305-1270. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703) 308-1152.

Any inquiry of a general nature or relating to the status of this application should be directed to the patent Analyst of the Art Unit, Ms. Chantae Dessau, whose telephone number is (703) 605-01237.



Frank Lu
July 26, 2002